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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,638	03/14/2001	Mary Faris	G&C 129.35-US-01	5083

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/809,638

Applicant(s)

FARIS ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 7, 14 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 7, 14 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment and Arguments

1. Claims 1, 7, 14 and 23 are pending.
Claims 2-4 have been cancelled.
Claims 7 and 23 have been amended.
Claims 1, 7, 14 and 23 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejection

Claim Rejections - 35 USC § 112

3. The rejection of claims 7 and 23 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of Applicants' arguments.
4. The rejection of claim 1 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn.

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5. The rejection of claim 14 under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure without complete evidence either that the claimed biological materials are known and readily available to the public or complete evidence of the deposit of the biological materials is withdrawn in light of the evidence provided by Applicants as Exhibit B.

6. The rejection of claims 2-4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention in light of the cancellation of the claims.

Claim Rejections - 35 USC § 102

7. The rejection of claims 14 and 23 under 35 U.S.C. 102(a) as being anticipated by Accession number Q9H720 (March 1, 2001), as evidenced by Accession number AK025164 (September 29, 2000) is withdrawn.

8. The rejection of claims 7, 14 and 23 under 35 U.S.C. 102(a) as being anticipated by Accession number AK025164 (September 29, 2000) is withdrawn.

Maintained and New Grounds of Rejection

Claim Rejections - 35 USC § 112

9. The rejection of claims 7, 14 and 23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained. Claims 2-4 have been cancelled.

Applicants submit, "...that [they] have not tested each and every 125P5C8 variant encompassed in the claims, however "that cannot be the test for 'possession'". Applicants aver that they have "...set forth claims that limit the claimed protein in terms of the type of substitutions..." and "...that one of skill in the art would recognize that the present claimed variants are supported by the present disclosure." Moreover, Applicants have submitted Exhibit A, an allowed claim from U.S. patent application 09/389,000 in support of their arguments. Applicants conclude arguments stating that "the presently amended claims are considered to be supported by a sufficient written description such that one of skill in the art would recognize that Applicants had possession of the claimed 90% variants of SEQ ID NO: 2." These arguments and points of view have been considered but found unpersuasive.

Applicants' claims are drawn to a genus. "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice...or by disclosure of relevant identifying characteristics, see Official Gazette, 1242: 174, January 30, 2001. Applicants

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have not met that requirement. The assertion that the protein is specifically bound by an antibody that specifically binds a 125P5C8 protein having the amino acid sequence of SEQ ID NO: 2 is not sufficient in meeting this requirement, see Paper number 22, mailed October 7, 2003, bridging paragraph of pages 5 and 6. Furthermore, within this genus is a substantial variation. There are at least 69 amino acids that must be mutated or changed to meet the conditions of the claims. The Official Gazette plainly establishes that "one must describe a sufficient variety of species to reflect the variation within the genus" especially if a claimed invention is in an unpredictable art, see 1242 OG 174, column 1, section 2. Applicants have not disclosed a representative number of species contained within this entire genus. Moreover, Applicants have not sufficiently described or fully characterized the claimed protein, therefore an attempt to define the unknown by binding specificity is not sufficient support for the claimed genus.

Applicants' situation is analogous to Enzo Biochem v. Gen-Probe, Inc., 323 F.3d 956, 964 (Fed. Cir. 2002) ("Enzo Biochem II"). It was stated that "the written description requirement would be met for all of the claims [of the patent at issue] if the functional characteristic of [the claimed invention was] coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed." [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. Noelle argues that because antibodies are defined by their binding affinity to antigens, not their physical structure, he sufficiently described human CD40CR antibody by stating that it binds to human

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CD40CR antigen. Noelle cites Enzo Biochem II for this proposition. This argument fails, however, because Noelle did not sufficiently describe the human CD40CR antigen at the time of the filing of the '799 patent application. In fact, Noelle only described the mouse antigen when he claimed the mouse, human, and genus forms of CD40CR antibodies by citing to the ATCC number of the hybridoma secreting the mouse CD40CR antibody. If Noelle had sufficiently described the human form of CD40CR antigen, he could have claimed its antibody by simply stating its binding affinity for the "fully characterized" antigen. Noelle did not describe human CD40CR antigen. Therefore, Noelle attempted to define an unknown by its binding affinity to another unknown. As a result, Noelle's claims to human forms of CD40CR antibody found in his '480 application cannot gain the benefit of the earlier filing date of his '799 patent application.

Moreover, Noelle cannot claim the genus form of CD40CR antibody by simply describing mouse CD40CR antigen.

As far as claim 38 from the allowed U.S. Application 09/389,000 the merits and the prosecution of one case have no bearing on the prosecution of the instant application. For the analysis set forth above and the reasons of record this rejection is maintained.

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10. The rejection of claims 7, 14 and 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement commensurate with the scope of the claimed invention is maintained. Claims 2-4 have been cancelled.

Applicants argue that the "presently claimed 125P5C8 protein variant are intended to encompass a set that maintains similar activities to that of the native protein and...account for the possibility that similar proteins (to SEQ ID NO: 2) containing allelic variations, for example, may exist". Applicants continue to aver that routine experimentation would confirm that given the limitations of the present claims and the supporting description, a variant having a significant alteration in the intrinsic activity would fall outside of the scope of the present claims. And "[m]oreover, the conservative substitution limitation is intended to allow for allelic variations, while preserving the activity of the protein." These points of view have been considered, but found unpersuasive.

Applicants assert that routine experimentation would provide establishing whether or not a variant is able to function as a useful diagnostic and/or therapeutic target for cancers of the prostate, bladder, kidney and colon, see page 2, lines 15-20; Table 1 on page 73. The Examiner has reviewed the specification and has not noted any guidelines or assays that allow one of ordinary skill in the art verify the function of the claimed mutant and variant proteins in order to eliminate functional molecules from those that have no bearing on the management of the various cancers listed.

Furthermore, if one assay was provided it not clear if wild type molecules, SEQ ID NO:

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1 and SEQ ID NO: 2 are efficient as a target for diagnostic, prognostic, preventative and therapeutic purposes. In regard to the conservation substitutions which Applicants assert provide limitations of the present claims the issue is not definite. On page 20 of the specification, lines 4-19 Applicants indeed provided examples of conservative substitutions, however "...other changes can be considered 'conservative' in particular environments", see specifically lines 16-19. In essence the conservative substitutions are not limited to one concise set of changes. It continues to be an arduous task and extensive experimentation would be required to enable the claims and practice the invention as claimed.

Claim Rejections - 35 USC § 102

11. The rejection of claim 7 under 35 U.S.C. 102(a) as being anticipated by Accession number Q9H720 (March 1, 2001), as evidenced by Accession number AK025164 (September 29, 2000) is maintained. Claims 2-4 have been cancelled.

Applicants argue that "[t]he polypeptide encoded by Q9H720 contains non-conservative substitutions versus the currently claimed proteins..." and these substitutions have defined on page 20 of the instant specification. Applicants further assert that Accession #Q9H720 does not disclose a polynucleotide having the sequence as shown in Figure 2 (SEQ ID NO: 1). Applicants' arguments and points of view have been considered and found to be persuasive in part.

The Examiner acquiesces to the fact that Accession #Q9H720 does not disclose the polynucleotide sequence shown in Figure 2 (SEQ ID NO: 1), however the said

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accession number does disclose an isolated 125P5C8 protein that is at least 99% identical to the amino acid sequence of SEQ ID NO: 2 over the entire length of SEQ ID NO: 2 wherein the amino acid substitution at position 689 is conservative, see sequence alignment between Q9H720 and SEQ ID NO: 2 mailed..... On page 20, lines 4-19 Applicants do list substitutions that can be considered conservative, as well as suggest that other changes can be considered 'conservative' in particular environments". The specification does not define what are particular environments and furthermore do not limit changes that can be regarded as conservative substitutions. Furthermore, the Examiner has reviewed the book edited by Stryer and it does not provide further clarification to the claims. The patent office implements the BLOSUM matrices as cited in the Henikoff PNAS paper and referred to by Applicants on line 18 of the specification and of record as Table II, page 74. The change from asparagine to histidine is regarded as a conservative substitution. Moreover, given the latitude of Applicants discussion of conservative substitutions in the specification the disclosed protein anticipates Applicants' claim. This protein would specifically be bound by an antibody that specifically binds a 125P5C8 protein having the amino acid sequence of SEQ ID NO: 2.

12. The rejection of claim 7 under 35 U.S.C. 102(a) as being anticipated by Accession number AK025164 (September 29, 2000) is maintained. Claims 2-4 have been cancelled.

Applicants' arguments are the same as that stated above in paragraph 11. The database sheet of Accession number AK025164 sets forth the amino acid protein that is

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at least 90% identical to the amino acid sequence of SEQ ID NO: 2 in the features section, as well as in the alignment. The rejection is maintained for these reasons.

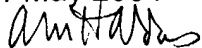
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The examiner works a flexible schedule, however can normally be reached between the hours of 7:00 am to 4:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Y. Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alana M. Harris, Ph.D.

11 May 2004



ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER